

Notice of Allowability

Application No.

10/089,367

Examiner

S. Devi, Ph.D.

Applicant(s)

RAPPUOLI ET AL.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' after-final amendment filed 06/21/07.
2. ☒ The allowed claim(s) ~~is/are~~ 35-43, now renumbered as claims 1-9 respectively.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

ATTACHMENT TO NOTICE OF ALLOWABILITY

Applicants' After-Final Amendment

1) Acknowledgment is made of Applicants' after-final amendment filed 06/21/07 in response to the final Office Action mailed 01/04/07. The amendment has been entered.

Examiner's Amendment

2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Ms. Roberta Robins in a telephonic interview on 02 July 2007.

The instant application has been amended as indicated below.

(A) Claims 1-9, 21-25 and 27 have been canceled.

(B) New claims 35-43 have been added as indicated below.

--Claim 35 (New). An intranasal vaccine comprising:

a diphtheria toxoid, a tetanus toxoid, and an acellular pertussis antigen (DTPa) comprising detoxified pertussis holotoxin; and

a detoxified *E. coli* heat labile toxin, wherein the detoxified *E. coli* heat labile toxin is LT-K63 or LT-R72.

Claim 36 (New). The intranasal vaccine of claim 35, wherein the acellular pertussis antigen comprises filamentous haemagglutinin.

Claim 37 (New). The intranasal vaccine of claim 36, wherein the acellular pertussis antigen further comprises pertactin.

Claim 38 (New). The intranasal vaccine of claim 36, wherein the detoxified pertussis holotoxin is 9K/129G double mutant.

Claim 39 (New). The intranasal vaccine of claim 35, wherein the diphtheria toxoid is CRM197.

Claim 40 (New). The intranasal vaccine of claim 35 further comprising at least one additional non-DTP antigen which does not diminish the immune response against said DTPa.

Claim 41 (New and rejoined). A method of generating an immune response against diphtheria, tetanus, and whooping cough in a patient comprising intranasally administering to the patient the vaccine of claim 35.

Claim 42 (New and rejoined). The method of claim 41, wherein the patient is a child.

Claim 43 (New and rejoined). The method of claim 41, wherein the intranasal administration is performed at least twice.--

Status of Claims

3) Claims 1-9, 21-25 and 27 have been canceled via this Examiner's amendment.

New claims 35-43 have been added via this Examiner's amendment.

Claims 41-43 have been rejoined with the examined product claims as per *In re Ochiai*. The restriction/lack of unity requirement set forth on method claims is hereby withdrawn.

Claims 35-43 are pending and are under examination.

Finality of Final Rejection is Proper

4) Applicants allege that the Office Action mailed 01/04/2007 was not properly made final.

Applicants state that the rejection of claims under 35 U.S.C. § 103 was presented for the first time therein, which could have been asserted previously. Applicants argue that the Office cannot, in the final rejection, state a new rejection that could have been asserted previously, without giving Applicants an opportunity to address the same. Applicants assert that such is an abridgment of Applicants' right to due process. Applicants submit that claim 1 was amended to incorporate the substance of claim 10 and that the remaining claim amendments were made in order to spell out abbreviations. Applicants state that claim 10 was not subject to any rejections under 35 U.S.C. § 103(a). Applicants argue that since the substance of claim 1 is essentially that of previous claim 10, the Office could have brought this 103 rejection in the last Office Action.

Applicants' arguments have been carefully considered. The finality of the Office Action mailed 01/04/07 is proper and is in full compliance with MPEP 706.07(a). Contrary to Applicants' assertion, the substance of claim 1 as presented via the amendment filed 10/31/06 was not essentially that of previous claim 10, because the vaccine of the original claim 10 and claim 1 comprised a diphtheria antigen, a tetanus antigen, an acellular pertussis antigen, a detoxified *E. coli* LT-K63 and LT-R72 mutants. No art rejections were made on the original claims 1-10. Applicants' amendment filed 10/31/06 canceled claim 10 and amended claim 1 to not only incorporate the substance of claim 10, not only spell out abbreviations, but additionally to change the entire scope of claim 1 substantially by replacing the limitation 'and' with the alternate limitation "or" in between the limitations 'LT-K63' and 'LT-R72'. This scope-changing amendment to claim 1 now required the

presence of either LT-K63 or LT-R72 in the claimed vaccine as opposed to the previously required presence of both LT-K63 and LT-R72. This very amendment to claim 1 made by Applicants via their amendment filed 10/31/06 necessitated the new art rejections in the Office Action mailed 01/04/07. These art rejections could not have been presented in the previous Office Action. Therefore, contrary to Applicants' allegations, the finality of the Office Action mailed 01/04/2007 is proper as is permitted by MPEP 706.07(a).

Rejection(s) Moot

- 5) The rejection of claims 1-6, 8 and 9 made in paragraph 14 of the Office Action mailed 01/04/07 under 35 U.S.C. § 103(a) as being unpatentable over Ryan *et al.* (*Immunology Lett.* 69: 59, # 11.19, June 1999, already of record) in view of Marsili *et al.* (EP 0 462 534 A2, already of record), is moot in light of the cancellation of the claims.
- 6) The rejection of claim 7 made in paragraph 14 of the Office Action mailed 01/04/07 under 35 U.S.C. § 103(a) as being unpatentable over Ryan *et al.* (*Immunology Lett.* 69: 59, # 11.19, June 1999, already of record) as modified by Marsili *et al.* (EP 0 462 534 A2, already of record) as applied to claims 6 and 1 above, and further in view of Metcalf (US 5,614,382, already of record) and Podda *et al.* (*Ann. Ig.* 3: 79-84, 1991, already of record), is moot in light of the cancellation of the claim.

Rejoinder

- 7) Pursuant to the procedures set forth in the *Official Gazette Notice* dated March 26, 1996 (1184 O.G. 86), claims 41-43, directed to a method of using the patentable intranasal vaccine, previously withdrawn from consideration as a result of lack of unity, is now subject to being rejoined. Claims 41-43 are hereby rejoined and fully examined for patentability under 37 C.F.R. 1.104.

Remarks

- 8) Claims 35-43, now renumbered as claims 1-9 respectively, are allowed.
- The descriptive support for new claims 35-40 can be found in the canceled claims 1-9, original claims 1-19, lines 14-26 of page 2, and Examples of the instant specification. The descriptive support for new claims 41-43 can be found in the canceled claims 21-23 and 27, the paragraph bridging pages 2 and 3, Figures and Figure descriptions, and Examples of the instant specification.
- 9) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted to the fax number (571) 273-8300 which receives papers

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24 hours a day, seven days a week.

10) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

July, 2007


S. DEVI, PH.D.
PRIMARY EXAMINER